

## **REMARKS**

### **Formal Matters**

Claims 17-36 are pending.

Claims 17-26, 30 and 32 were examined and rejected.

Claims 17, 19 and 32 are amended for clarity. No new matter is added.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### **Interview Summary**

Examiner Wessendorf is thanked for the telephonic interview with Applicants' representatives James Keddie, Carol Francis and James Diehl.

The current enablement rejection was discussed in detail. No agreement was reached.

The Applicants requested further clarification of the current enablement rejection from SPE Paras on July 10, 2006. On July 19, 2006, Exr. Paras stated he had met with Exr. Wessendorf, and that the current enablement rejection would be withdrawn upon receipt of this response.

### **Restriction/Election**

The Examiner is thanked for clarifying the Office's reasoning for the previous Restriction Requirement and species election.

The Examiner is reminded that upon election of a species for initial examination, the Examiner's actions must conform to MPEP §809.02(c). If the generic claim, in this case claim 17, is allowable, the election of species must be withdrawn.

As elaborated in the prior response, the Applicants respectfully disagree with the Restriction Requirement and species election. Applicants expressly reserve the right under 37 C.F.R. § 1.144 to petition the Director to review the Restriction Requirement and species election during the pendency of this application.

The Applicants would be happy to submit a Terminal Disclaimer in this case if the current claims are deemed allowable.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claims 17-26, 30 and 32 are rejected under 35 U.S.C. § 112, first paragraph, because the specification assertedly does not enable one of skill in the art to make and use the claimed subject matter.

The Applicants reiterate their prior arguments regarding this rejection, as set forth on pages 6-12 of their prior response. For the sake of brevity, those arguments are not set forth below.

As noted above, in a telephonic interview with Exr. Paras on July 19, 2006, Exr. Paras stated that he had met with Exr. Wessendorf and discussed the rejection. Exr. Paras stated that this rejection would be withdrawn.

Withdrawal of this rejection is requested.

**New matter**

Claim 32, reciting the phrase “a p21 fragment, a p21 mutant, or a p21 mutant fragment” is rejected as containing new matter.

Without any intention to acquiesce to the correctness of this rejection and solely to expedite prosecution, claim 32 has been amended to delete the phrase “a p21 fragment, a p21 mutant, or a p21 mutant fragment”.

This rejection may be withdrawn.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claims 19, 25-26 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being indefinite.

Claim 19 is rejected as indefinite because there appears to be no antecedent support for the phrase “said fusion partner”.

Claim 19 has been amended to be dependent on claim 18. Since the phrase “a fusion partner” is found in claim 19, this rejection may be withdrawn.

Claim 25 is rejected as indefinite because it is allegedly being inconsistent with independent claim 17. In essence, the Examiner request clarification of how a claim that recites a *single* phenotype (exocytosis) can be dependent on a claim that requires the use of *five* FACS parameters.

The Applicants submit that claim 25 is consistent with claim 17 because an alteration in exocytosis can be detected using at least five FACS parameters, e.g., five FACS parameters selected from forward light scattering, forward light scattering, fluorescent dye uptake, fluorescent dye release, annexin granule binding and surface granule enzyme activity, etc.

In view of the foregoing discussion, this rejection may be withdrawn.

Claim 26 is rejected as indefinite because it is assertedly unclear as to whether the listed parameters “are different species of the parameters recited in claim 17 or the five parameter-itself”.

The Applicants confess to not fully understanding the basis for this rejection. However, the Applicants assert that claim 26 is clarified by the following statement: the five parameters can be selected from the six parameters listed in claim 26 to detect exocytosis according to the method of claim 17.

The Applicants submit that this rejection has been addressed by the statement. If this rejection is to be maintained, the Applicants request that the Examiner clarify the rejection.

Claim 32 is rejected as indefinite because it is not clear to the Examiner how a mutant or a fragment of a mutant can be used as a positive control

As noted above, claim 32 has been amended to remove reference to a mutant or a fragment of a mutant.

As such, this rejection is believed to be moot and may be withdrawn.

### **Obviousness-Type Double Patenting**

Claims 17-26, 30 and 32 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of 09/157,748 (now U.S. Patent 6,461,813) and 09/062,330 (now U.S. Patent 6,897,031).

Again, the Applicants request that this rejection be held in abeyance until allowable subject matter is identified in this application.

### **Rejection under 35 U.S.C. § 103 - Lorens**

Claims 17-26, 30 and 32 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. patent application 09/157,748 (now U.S. Patent 6,461,813 and referred to herein as “Lorens”).

The Applicants note the present application as filed claims priority to U.S. patent application 09/157,748 (now U.S. Patent 6,461,813). This priority claim was inadvertently omitted from the Official Filing Receipt, and a request for a corrected Official Filing Receipt is submitted herewith. As such, the cited patent application is a parent of the instant case.

Further, the Applicants submit that the subject matter of the cited Lorens patent and the claimed invention were, at the time the claimed invention was made, assigned or under obligation of assignment to Rigel. Pursuant 35 U.S.C. § 103(c) Lorens cannot preclude the patentability of the presents claims. This rejection may be withdrawn.

Support for this assertion is set forth below:

35 U.S.C. § 103 (a) states that a patent may not be obtained if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made<sup>1</sup>. 35 U.S.C. § 103 (c)(1), however, states that subject matter developed by another person shall not preclude patentability under 103(a) where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.<sup>2</sup>

According to 35 USC § 103(c), therefore, the Lorens patent cannot preclude the patentability of the rejected claims if the Lorens patent and the instant application were assigned to the same person or subject to an obligation of assignment to the same person, at the time the instant claimed invention was made.

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<sup>1</sup> 35 U.S.C. § 103(a) : A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

<sup>2</sup> 35 U.S.C. § 103(c)(1): Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The invention claimed in the instant patent application was owned by Rigel Pharmaceuticals, Inc. (“Rigel”) or subject to an obligation of assignment to Rigel at the time the instant claimed invention was made, as evidenced by an assignment executed by the inventors (Reel/Frame 010189/0486).

The Lorens patent was owned by Rigel or subject to an obligation of assignment to Rigel at the time the instant invention was made, as evidenced by an assignment executed by the inventors (Reel/Frame 013600/0798).

Thus, the Lorens patent and the claimed invention were, at the time the invention was made, assigned or under obligation of assignment to Rigel. Accordingly, Lorens cannot preclude patentability of the instant claims under 35 U.S.C. § 103(a).

In view of the disqualification of Lorens as a prior art reference, this rejection should be withdrawn.

**Rejection under 35 U.S.C. § 103 – Nolan in view of Jai-ping or Ryan**

Claims 17-25, 30 and 32 are rejected under 35 U.S.C. § 103(a) as being obvious over Nolan (WO97/27212) in view of Jai-ping or Ryan.

Since Nolan’s publication date (July 31, 1997) predates the earliest priority date of this application (April 17, 1997), Nolan qualifies as prior art only under 35 U.S.C. § 102(a)<sup>3</sup>. Thus, Nolan is citable under 35 U.S.C. 103(a) as “102(a)-type”.

A declaration is submitted herewith under 35 U.S.C. § 1.131 to establish invention of the subject matter of the rejected claims prior to the Nolan’s publication date. Since Nolan’s publication date is antedated by the Inventor’s activities, Nolan cannot preclude the patentability of the rejected claims as 102(a)-type art.

Support for the Applicants position is set forth below.

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<sup>3</sup> The PCT application upon which Nolan’s publication (WO97/27212) is based was filed on January 23, 1997. Nolan’s filing date is *prior to* the November 19, 2000 date of enactment of amended 35 U.S.C. § 102(e). As such, Nolan is not available as prior art as of its filing date, and is not citable as “102(e)-type art”. The Applicants analysis is supported by MPEP § 2136.03.II.(C)(2).

**Nolan cannot preclude the patentability of the rejected claims as 102(a)-type art**

As set forth in 37 C.F.R. §1.131:

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§1.42, 1.43, or 1.47, ***may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference*** or activity on which the rejection is based. . . .

(b) ***The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.*** Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.  
(emphasis added)

As such, Nolan may be antedated by means of a declaration and a showing of facts, that the claimed subject matter was conceived prior to July 31, 1997 (Nolan's publication date), and diligently reduced to practice.

In order to establish that the claimed invention was conceived prior to July 31, 1997, and diligently reduced to practice, the Applicants submit herewith the Declaration of Dr. Joseph Fisher under 37 C.F.R. §1.131.

The Applicants respectfully submit that Dr. Fisher's declaration and attached exhibits demonstrate conception of the claimed subject matter prior to July 31, 1997, and diligent reduction to practice from July 31, 1997 to September 8, 1997

Exhibit A is dated prior to July 31, 1997. Exhibit A demonstrates that the Inventors, as part of a research program to identify retrovirally-delivered bioactive peptides, had sorted a cell population contacted with A23187, an inducer of exocytosis, using at least *five* FACS parameters. The Applicants submit that Exhibit A demonstrates that the Inventors had conceived the subject matter of the rejected claims prior to July 31, 1997.

Exhibit B is dated from August 22, 1997 to August 27, 1997. Exhibit B is a document demonstrating that the Inventors transfected mammalian cells with a library of retroviral vectors that

encode candidate bioactive peptides. The Applicants submit that Exhibit B demonstrates that the Inventors diligently worked towards an actual reduction to practice between July 31, 1997 to August 27, 1997.

Exhibit C is dated September 8, 1997. Exhibit C is a document demonstrating that the Inventors sorted a population of cells that had been transfected with a library of retroviral vectors that encode candidate bioactive peptides, using at least five FACS parameters. Thus, Exhibit C demonstrates an actual reduction to practice of what is being claimed.

In view of the foregoing discussion and the accompanying Declaration and Exhibits, the Applicants submit that they conceived of the invention prior to the effective date of Nolan (July 31, 1997) and diligently worked towards a reduction to practice of the invention at least as early as September 8, 1997.

Accordingly, since the Applicants have provided an appropriate declaration and showing of facts that establish conception of the invention prior to the date at which Nolan is citable under 35 U.S.C. 102(a), i.e., July 31, 1997, coupled with due diligence from prior to that date to an actual reduction to practice at least as early as September 8, 1997.

As such, Nolan cannot preclude the patentability of the rejected claims as 102(a)-type art under 35 U.S.C. §103(a).

Thus, although Nolan is correctly citable as art under 35 U.S.C. § 103(a), it cannot preclude the patentability of the instant claims.

Withdrawal of this rejection is respectfully requested.

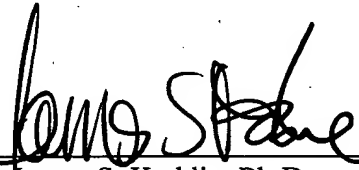
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-036CIP.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: \_\_\_\_\_

July 24, 2006

By: \_\_\_\_\_



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